PATENT

In the UNITED STATES PATENT and TRADEMARK OFFICE

APPLICANT: Ndife, et al	EXAMINER: Helen F. Pratt ART UNIT: 1761
SERIAL NO.: 10/603,464	DOCKET NO.: 6953US01
FILED: June 25, 2003	I certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service with sufficient postage as first class mail addressed to the Commissioner for Patents, Alexandria, VA, on the date shown below.
TITLE: **INFANT FORMULA**	Wendy Detwiler 9-24-04 Wendy Detwiler Date

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF

Dear Sir:

This is an appeal of Claims 1-11 and 14, which were finally rejected by the Examiner in an Office Action dated July 19, 2004 in the above-entitled application. This Appeal Brief (triplicate copies enclosed) is submitted concurrently with the enclosed Notice of Appeal.

Real Party in Interest

The above-entitled Application has been assigned to Abbott Laboratories, 100 Abbott Park Road, Abbott Park, Illinois 60064. The inventors, Louis I. Ndife, Booker T. Lucas III, and Stephene L. Hohman, have assigned their interests to Abbott Laboratories, in an assignment recorded in the United States Patent Office on January 26, 2004, at reel 014923, frame 0274 (3 pages).

Related Appeals and Interferences

There are no prior or pending appeals, interferences or judicial proceedings known to appellant, the appellant's legal representative, or assignee which may be related to, directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

Status of Claims

Claims 1-11 and 14 have been finally rejected but remain pending. Claims 12, 13, and 15 have been cancelled, without prejudice.

Status of Amendments

All amendments to the claims have been entered, and no amendments have been made to the claims as of July 19, 2004, the date of the Final Office Action rejecting all claims from which this appeal is made.

Summary of Claimed Subject Matter

The present invention is directed to infant formula tablets (independent claims 1 and 14) and a method of providing nutrition to an infant from a reconstituted formula derived from the tablets (method claim 11).

The infant formula tablet of claim 1 comprises from 10-20 w/w % protein (see page 10, line 5); from 40-70 /w% carbohydrate (see page 10, line 6); and at least 20 w/w% fat (see page 10, line 7); wherein the tablet is formed under a pressure selected from within a range of from about 400 psi to about 1500 psi (see page 12, lines 15-19), and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface (see page 3, lines 2-6), and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a manual dissolution test (see page 3, lines 28-34; page 10, line 2).

The infant formula tablet of claim 14 comprises on a 100 kcal basis from about 8 to about 16 grams of carbohydrate, from about 3 to about 6 grams of fat, and from about 1.8 to about 3.3 grams of protein (see page 9, lines 31-34; page 10, lines 1 and 2), wherein the tablet is formed under a pressure selected from within a range of from about 400 psi to about 1500 psi (see page 12, lines 15-19), and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface (see page 3, lines 2-6), and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a mechanical dissolution test (see page 10, line 2).

Grounds of Rejection to be Reviewed on Appeal

In the July 19, 2004 Final Office Action, Claims 1-11 and 14 were rejected under 35 USC 103(a) as being unpatentable over U.S. Patent 3,241,975 (Brochner) in view of WO 03/077664 (Ozalvo et al.) and Merck Index, page MISC-87. In setting forth the rejection, the Examiner contends:

"Claims 1 and 14 have been amended to require a particular psi of from 400 to 1500. However, Ozalvo et al. disclose a compressing weight of 0.25 tons which multiplied by 2000 tons gives a psi (lbs per square inch) of 500 which is within the claimed range (Merck Index conversion table). Therefore, it would have been obvious to use a known compressing weight in the process of Brochner as shown by Ozalvo et al. who also makes a tabletted baby formula." (see July 19, 2004 Final Office Action, at page 2)

and

"Applicants argue that Ozalvo et al. and Brochner are silent as to the problem of making infant formulas into tablets with high fat concentrations. This is not seen because Brochner discloses a compressed tablet as above and Ozalvo discloses a baby formula which uses the claimed psi." (see July 19, 2004 Final Office Action, at page 2)

Argument

The subject matter as recited in Applicants' Claims 1-11 and 14 would not have been obvious under 35 USC 103 over Brochner in view of Ozalvo et al and Merck.

Brochner discloses milk tablets for use and dissolution in warm aqueous liquids such as coffee, tea, and cocoa. The tablets comprise 10-29% butter fat, 7-15% milk protein, 15-65% carbohydrates and other minor ingredients and water (see Brochner, page 1, lines 84-88). Brochner teaches the manufacture of a readily soluble milk tablet formed by the compression of powdered milk (SEE Brochner, page 1, lines 51-65).

Ozalvo et al. discloses reconstitutable tablets for use in preparing an infant formula prior to feeding. The tablets are preferably fast dissolving, which is accomplished according to Ozalvo et al. by designing different tablet shapes to have a larger surface to volume ratio (see Ozalvo et al., page 6, lines 5-9).

Merck discloses a conversion chart for converting a variety of different pressure values or units.

None of the applied references, taken alone or in combination, disclose or suggest that infant tablet dissolution can be greatly improved upon by controlling tabletting pressure. Ozalvo et al. teach that tablet dissolution can be improved by increasing the tablet surface area to volume

ratio. Brochner is silent as to how to improve tablet dissolution. And Merck only provides a conversion table- nothing more.

Applicants have found that tablet dissolution rates can be dramatically and undesirably slowed if the tabletting pressures are allowed to reach a threshold at or above which a fatty or oily film forms on the exterior surface of the tablets. This key finding is reflected as a limitation in all of Applicants' remaining claims, wherein the infant formula is a tablet formed under a pressure selected from within a range of from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a manual dissolution test.

This particular problem associated with the development of an oily film around an infant formula tablet was not disclosed or suggested by any of the applied prior art references. It is well established that the solution to an unobvious problem can provide the basis for patentability of an otherwise novel product form, whether or not the solution itself is an obvious one. Although infant formula tablets are known, the problem of tablet dissolution caused by fatty films around these tablets was not previously known, nor was the solution of controlling tabletting pressures to avoid the oily films around the tablets.

The Examiner also contends that it would have been obvious in view of the applied prior art references to formulate an infant formula tablet with Appellant's tabletting pressure of from about 400 psi to about 1500 psi, especially since Ozalvo et al. describes a tabletting pressure of 500 psi. The Examiner's contention in this particular instance is erroneous for the following reasons.

First, the Examiner appears to be focusing on the range of tabletting pressures, and has overlooked the other claim limitation which states "...and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface..." (see Claims 1 and 14). In other words, Applicants are not claiming that all tabletting pressures between 400 and 1500 psi will work for the recited formula, but rather that the tabletting pressure must be selected from within that range and must be selected so as not to result in an oily film around the tablet.

Second, the Examiner incorrectly attributed Ozalvo et al., in view of Merck, with a tabletting pressure of 500 psi. The only tabletting pressure suggested by the applied prior art was that noted by Ozalvo et al. at page 11, lines 3-6 (0.25 tons applied to a 2 gm tablet). It is unclear from the description exactly what pressure was actually applied (i.e., psi value) to the Ozalvo et al. tablet, since such pressure can be affected by factors such as the topical area of the tablet form as well as the configuration or size of the tablet punch used in the press. Ozalvo et al., of course,

made no provision whatsoever for controlling or adjusting such pressures for any purpose, and certainly didn't suggest any such control or adjusting to avoid the formation of a fatty or oily film on the tablet surface (which would then slow down tablet dissolution rates).

The examiner, however, incorrectly states that the tabletting pressure disclosed by Ozalvo et al. can be converted from 0.25 tons to 500 psi (pounds per square inch) by using the Merck Index conversion table. Merck, however, only discloses how to convert from tons to pounds (pressure to pressure), not from tons to psi (pressure to pressure per unit area). Applicants' submit that the conversion suggested by the Examiner (0.25 tons to 500 psi) is erroneous and without any support from the prior art of record.

Conclusion

In short, the tabletting pressures attributed to Ozalvo et al. by the Examiner appear to be erroneous, and should not be used as a basis for rejecting Applicants' claims. Moreover, the applied prior art references together fail to disclose or suggest the tablet dissolution problem that arises with these infant formula tablets when a fatty or oily film is unknowingly formed around the tablet due to excessive tabletting pressures. And neither reference, of course, suggests any solution to such a problem, let alone Applicants' solution of selecting tabletting pressures while also monitoring the tabletting process to avoid the development of an exterior fatty or oily film.

Accordingly, Appellant respectfully request that the honorable Board of Appeals and Interferences reverse the Examiners rejection and remand with directions to allow the above-entitled Application to issue with Claims 1-11 and 14 as currently pending.

Respectfully submitted,

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Claims Appendix

1. An infant formula in tablet form comprising:

a) a source of protein, present in the amount of 10 to 20 w/w %;

b) a source of carbohydrate, present in the amount of 40 to 70 w/w%; and

c) a source of fat present in the amount of at least 20 w/w%;

wherein the infant formula is a tablet formed under a pressure selected from within a range of from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a manual dissolution test.

2. The formula according to claim 1 in which said fat is present in the quantity of at least 25 w/w%.

3. The formula according to claim 1 in which said protein is present in the quantity of 11 to 16 w/w%

4. The formula according to claim 1 in which said carbohydrate is present in the quantity of about 50 to 60 w/w%.

5. The formula according to claim 1 in which said protein is selected from the group consisting of intact protein, hydrolyzed protein and amino acids.

6. The formula according to claim 1 wherein the protein comprises intact protein selected from the group consisting of soy based protein, milk based protein, casein protein, whey protein, rice protein, and pea protein.

7. The formula according to claim 1 wherein the protein comprises hydrolyzed protein selected from the group consisting of soy protein hydrolysate, casein protein hydrolysate, whey protein hydrolysate, and rice protein hydrolysate,

8. The formula according to claim 1 wherein the protein comprises free amino acids selected from the group consisting of L-tryptophan, L-tyrosine, L-cystine, L-taurine, L-methionine, L-arginine, and L-carnitine.

9. The formula according to claim 1 wherein the carbohydrate is selected from the group consisting of hydrolyzed, intact, natural and chemically modified starches sourced from corn, tapioca, rice or potato in waxy or non waxy forms; sugars such as glucose, fructose, lactose, sucrose, maltose, high fructose corn syrup; and mixtures thereof.

10. The formula according to claim 1 wherein the fat is selected from the group consisting of coconut oil, soy oil, corn oil, olive oil, safflower oil, high oleic safflower oil, medium chain triglyceride oil, sunflower oil, high oleic sunflower oil, palm oil, palm olein, canola oil, arachidonic acid and docosahexaneoic acid.

11. A method for providing nutrition to an infant comprising dissolving the tablet of claim 1 and feeding the resulting formula to an infant in need thereof.

14. An infant formula in tablet form comprising, based on a 100 kcal basis:
a) about 8 to about 16 grams of a source of carbohydrate,
b) about 3 to about 6 grams of a source of fat, and
c) about 1.8 to about 3.3 grams of a source of protein,
wherein the infant formula is a tablet formed under a pressure selected from within a range of from about 400 psi to about 1500 psi, and wherein the pressure is selected so that a film of fat does not form on the exterior tablet surface, and wherein the resulting infant formula tablet dissolves within 60 seconds in accordance with a mechanical dissolution test.